SUMMARY

spesolimab

SPEVIGO 450 mg,

solution for infusion

First assessment

Original French opinion adopted by the Transparency Committee on 1 April 2023

The legally binding text is the original French opinion version

Key points

Favourable opinion on reimbursement in " The treatment of flares in adult patients with generalised pustular psoriasis (GPP) as monotherapy."

What therapeutic improvement?

Improvement in management strategy.

Role in the care pathway?

SPEVIGO (spesolimab) is the first medicinal produced indicated in the treatment of flares of generalised pustular psoriasis.

The clinical data dealing with the concomitant use of other treatments for GPP with spesolimab are limited. In compliance with the SmPC, spesolimab must not be used with other treatments for GPP, such as systemic immunosuppressants, to treat a flare.

If the symptoms of the flare persist, an additional dose of 900 mg may be administered one week after the first dose.

The Committee considers that spesolimab (SPEVIGO) is a first-line treatment in the treatment of flares of generalised pustular psoriasis (GPP).

Transparency Committee's Conclusions

Clinical Benefit

- Generalised pustular psoriasis (GPP) is a rare inflammatory disease characterised by sudden flares in the form of non-infectious pustules on the skin, often associated with systemic signs (fever, extreme fatigue), with an unpredictable course and complications that can be potentially serious and lead to death.
- It is a suspensive symptomatic medicinal product.
- The efficacy/adverse effect ratio is significant in view of the substantial effect observed versus placebo for three endpoints assessing the clearance of pustules, the overall appraisal of disease severity by the doctor and disease severity in terms of the appearance and extent of the lesions and the acceptable tolerance profile.
- It is a first-line treatment in the treatment of flares of generalised pustular psoriasis (GPP).

Public health benefit

In view of:

- the gravity of the disease which can be life-threatening for patients and of its low prevalence,
- the partially met medical need,
- the partial response to the need identified:
  - an additional proven impact on morbidity but not on quality of life,
  - the absence of additional impact on the organisation of care,
  - the absence of impact on the patient's care pathway and life course,

SPEVIGO (spesolimab) is not liable to have an additional impact on public health.

In view of all of these elements, the Committee considers that the clinical benefit provided by SPEVIGO 450 mg (spesolimab), concentrate for solution for infusion, is significant in the MA indication.

The Committee gives a favourable opinion on the inclusion of SPEVIGO 450 mg (spesolimab), concentrate for solution for infusion on the list of medicinal products approved for the use of communities in the MA indication and at the MA doses.

Clinical Added Value

In view of:

- an unmet medical need in the treatment of GPP flares,
- the demonstration of the superiority of spesolimab 450 mg compared to placebo, with a significant effect, in adult patients with a moderate-to-severe flare of generalised pustular psoriasis in a randomised, double blind phase II, study, with regard to clinically relevant endpoints assessing the clearance of pustules at D8, the overall appraisal of disease severity by the doctor and disease severity according to the appearance and extent of the lesions,

but taking into account:

- the impossibility of interpreting the results for the subjective hierarchical secondary endpoints of the disease (pain score, PSS score and FACIT-Fatigue score), in view of the large number of non-responders in the placebo group in week 4,

the Committee considers that SPEVIGO 450 mg (spesolimab), concentrate for solution for infusion provides minor clinical added value (CAV IV) in the management of generalised pustular psoriasis flares in adults.